

## REMARKS

### I. PRELIMINARY REMARKS

No claims have been amended. Non-elected claims 38-42 and 46 been canceled. Claims 47-50 have been added. Claims 1-4, 7-15, 18-28, 30, 31, 34-37 and 47-50 remain in the application. Reexamination and reconsideration of the application, as amended, are respectfully requested.

### II. BRIEF DESCRIPTION OF AN EXEMPLARY EMBODIMENT

The present inventions, as defined by the claims, are directed generally to forming lesions in body tissue and determining whether or not therapeutic lesions have been formed. Referring to Figures 14 and 15, an exemplary suction device 404 includes a main body 407 with a plurality of suction ports 410 and slot 420. The slot 420 may be used as a connector to secure a portion of a surgical probe 100', with a plurality of electrodes 110, to the suction device 404. The suction device 404 may, in turn, be used to fix the position of the surgical probe 100' during a lesion formation procedure.

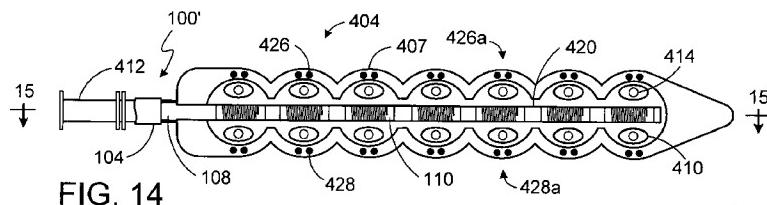


FIG. 14

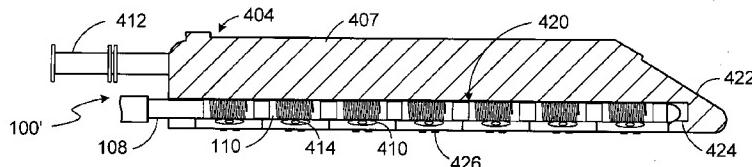


FIG. 15

The suction device 404 also includes stimulation electrodes 426 and sensing electrodes 428 on the main body 407. The slot 420 is between the stimulation electrodes 426 and the sensing electrodes 428 and, accordingly, the stimulation

electrodes 426 and sensing electrodes 428 will be on opposite sides of the lesions formed by the surgical probe 100'. The suction device 404 may be used to stimulate tissue on one side of the lesion, and sense tissue on the other side of the lesion, to determine whether or not a therapeutic lesion has been formed by the surgical probe 100'. [Specification at, for example, page 28, line 27 to page 30, line 28.]

### **III. PRIOR ART REJECTIONS**

#### **A. The Rejections**

Claims 1-4, 7-15, 18-28, 30, 31 and 34-37 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of U.S. Patent No. 6,364,876 to Erb ("the Erb patent") and U.S. Patent No. 6,558,382 to Jahns ("the Jahns patent"). The rejection under 35 U.S.C. § 103 is respectfully traversed. Reconsideration thereof is respectfully requested.

#### **B. The Cited References**

The vacuum assisted ablation device illustrated in Figure 13 of the Erb patent includes a helical antenna 23 (note reference numeral 23 in Figure 11A) on a shaft 31, and a shield assembly 25 that is disposed about the antenna 23. The shield assembly 25 includes a cradle device 26 with a window portion 27. A plurality of suction orifices 76 are positioned around the window portion 27.

The Jahns patent discloses a variety of "suction stabilized" ablation devices. Referring to Figure 4, which was identified in the Office Action, ablation device 12 includes an elongate electrode 422 that extends along one side of the device and a plurality of suction ports 444 that extend along the other side. Another ablation device is illustrated in Figure 5. Here, a plurality of needle electrodes 522 are spaced along the centerline of the device and a plurality of suction ports 544 are located along the centerline between the needle electrodes. The Jahns patent also discloses sensor devices. The sensor device 790

illustrated in Figure 7, which was referred to in the Office Action, is a **separate device** that may be employed in combination with, for example, the ablation device 12. [Note column 10, lines 10-20; column 12, line 63 to column 13, line 8; column 13, lines 45-66; Figures 4 and Figure 7.] The sensor device 790 includes a plurality of sensors 90 that extend along one side of the device and a plurality of suction ports 786 that extend along the other side.

### C. The Applicable Legal Standards

With respect to the legal standard upon which patentability under 35 U.S.C. § 103 is evaluated, *In re Kotzab*, 55 USPQ2d 1313, 1316-17 (Fed. Cir. 2000), provides a fairly succinct summary of the standard adhered to by the Federal Circuit:

A critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one “to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher.” Most if not all inventions arise from a combination of old elements. Thus, every element of a claimed invention may often be found in the prior art. However, ***identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. Rather***, to establish obviousness based on a combination of the elements disclosed in the prior art, ***there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant.*** Even when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference.

[Citations emitted, emphasis added.] The *Kotzab* decision is also cited in Section 2143.01 of the Manual of Patent Examining Procedure.

“The motivation, suggestion or teaching may come explicitly from statements in the prior art, the knowledge of one of ordinary skill in the art, or, in some cases, the nature of the problem to be solved. In addition, the teaching, suggestion or motivation may be implicit from the prior art as a whole, rather than expressly stated.” *In re Kotzab*, 55 USPQ2d at 1317. Whether the showing is explicit or implicit, “rejections on obviousness

grounds ***cannot be sustained by mere conclusory statements***; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *In re Kahn*, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), *citations omitted, emphasis added*. To that end, “particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected [the] components for combination in the manner claimed.” *In re Kotzab*, 55 USPQ2d at 1317. “This factual question of motivation is material to patentability, and ***[may] not be resolved on subjective belief and unknown authority***.” *In re Lee*, 61 USPQ2d 1430, 1434 (Fed. Cir. 2002), *emphasis added*.

#### D. Discussion Concerning Claims 1-4, 7-15, 18-28, 30, 31 and 34-37

Independent claims 1, 12 and 23 call for respective combinations that comprise, *inter alia*, “a main body,” “a suction region associated with the main body,” “a stimulation element on the main body,” “a stimulation energy sensing element on the main body” and “a connector, located between the stimulation element and the stimulation energy sensing element, configured to secure at least a portion of the electrophysiology device to the main body adjacent to the suction region.” The respective combinations defined by claims 2-4 and 7-11 include, *inter alia*, the elements recited in independent claim 1, the respective combinations defined by claims 13-15 and 18-22 include, *inter alia*, the elements recited in independent claim 12, and respective combinations defined by claims 24-28, 30, 31 and 34-37 include, *inter alia*, the elements recited in independent claim 23.

The cited references fail to teach or suggest the claimed combinations. For example, and as tacitly admitted in the Office Action, the Erb patent fails teach or suggest at least three aspects of the claimed combinations. Each of the Erb devices lacks both a “stimulation element” and a “stimulation energy sensing element.” As such, the Erb devices also lack a “connector [that is] located between the stimulation element and the stimulation energy sensing element.” The Jahns patent fails to remedy these deficiencies. Not only does the Jahns patent fail to teach or suggest placing a

“stimulation element” on one side of the “connector” associated with the Erb shield assembly 25 and a “stimulation energy sensing element” on the other side, the Jahns patent fails to so much as suggest placing a “stimulation element” and a “stimulation energy sensing element” on a device, such as the Erb shield assembly, that is connected to an ablation device. The Jahns patent merely suggest using suction to secure a sensing device, which is not connected to an ablation device, to tissue.

Despite the clear failure of the cited references to teach or suggest the claimed combinations, the Office Action asserted that the claimed combinations were rendered obvious because each of the Jahns figures “depicts a different embodiment in which the placement of suction ports and electrodes are varied” and “it would have been obvious to include the Jahns electrodes (522) adjacent the Erb suction ports (76) ... as yet another design variation in the spirit seen in Jahns ... to provide an additional embodiment as implied as beneficial through Jahns’ disclosure of numerous embodiments.” [Office Action at page 3.] Applicant respectfully submits that there are a number of errors associated with this assertion.

First, the Jahns patent only discloses a single suction/sensor embodiment, i.e. the embodiment illustrated in Figure 7, and it includes a plurality of sensors 90 that extend along one side of the device and a plurality of suction ports 786 that extend along the other side. Such an arrangement is, of course, vastly different than the claimed “stimulation element” and “stimulation energy sensing element” arrangement.

Second, the various locations of the electrodes in the Jahns ablation devices (e.g. electrodes 522) would not have suggested anything to the skilled artisan concerning the addition and/or location of a “stimulation element” and a “stimulation energy sensing element” on the Erb shield assembly 25.

Third, even assuming for the sake of argument that the Jahns ablation devices were relevant to the issue of obviousness, the teachings associated with the ablation devices fail to remedy the deficiencies in the Erb patent.

Finally, the Office Action appears to have taken the “novel” position that a reference which discloses a plurality of embodiments renders embodiments which are not disclosed or suggested obvious because (1) the disclosure of a plurality of embodiments in and of

itself implies that additional embodiments are beneficial and (2) the pursuit of the benefits associated with the additional embodiments would necessarily lead the skilled artisan to any and all non-disclosed and non-suggested embodiments. Applicant's undersigned representative is unaware of any support for this proposition in the United States Code, the Code of Federal Regulations, the case law, or the MPEP. In order to clarify the issues for appeal, applicant hereby requests that the Advisory Action, or other subsequent action, provide a citation in support of this proposition.

In view of the foregoing, applicant respectfully submits that the cited references fail to establish a *prima facia* case of obviousness and that the rejection of claims 1-4, 7-15, 18-28, 30, 31 and 34-37 under 35 U.S.C. § 103 should be withdrawn.

#### **IV. NEWLY PRESENTED CLAIMS 47-50**

Claims 47-49 respectively depend from independent claim 1, 12 and 23 and, therefore, are patentable for at least the same reasons as claims 1, 12 and 23.

Claim 50 calls for a combination of elements comprising "a main body defining a longitudinal axis," "a suction region associated with the main body," "a connector configured to secure at least a portion of the electrophysiology device to the main body adjacent to the suction region," "means, carried by the main body, for stimulating tissue that is adjacent to the main body and on one side of the longitudinal axis" and "means, carried by the main body, for sensing stimulation energy in tissue that is adjacent to the main body and on the other side of the longitudinal axis." Applicant respectfully submits that the references cited in the Office Action fail to teach or suggest the claimed combination and, accordingly, that claim 50 is patentable thereover.

#### **V. CLOSING REMARKS**

In view of the foregoing, it is respectfully submitted that the claims in the application are in condition for allowance. Reexamination and reconsideration of the

application, as amended, are respectfully requested. Allowance of the claims at an early date is courteously solicited.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is respectfully requested to call applicant's undersigned representative at (310) 563-1458 to discuss the steps necessary for placing the application in condition for allowance.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0638. Should such fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefor.

Respectfully submitted,

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Date

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